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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,354	03/26/2004	Andrew T. Beckman	END5095.0515520	1242

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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
03/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,354	BECKMAN ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73 and 75-96* is/are pending in the application.

4a) Of the above claim(s) *1-60, 62-64, 84-85, and 90-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61,65-73,75-83 and 86-89* is/are rejected.

7)☒ Claim(s) *65 and 71* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 12/10/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

In Applicant's reply filed 6/30/2008, Applicant elected (1) a hydrogel polymer and (2) hemostatic agents. Applicant has currently amended the claims and argues that claims 61, 65-73, 75-83 and 86-89 now encompass the elected species. The Examiner agrees and claims 61, 65-73, 75-83 and 86-89 are currently under consideration.

New Grounds of Rejection

Claim Objections

Claims 65 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 65 recites "the method of claim 61 wherein the biocompatible material comprises a polymer". The biocompatible material of claim 61 already comprises

a polymer according to the limitations of claim 61. Thus, claim 65 fails to further limit claim 61.

Claim 71 is objected to because of the following informalities: The claim ends with a comma instead of a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67-73 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 recites "wherein the polymer is a polyvinyl alcohol gel, foam, sponge, swellable polymer, hydrogels and acylation derivatives thereof, including esters". The claim is indefinite for the following reasons (1) It is unclear if "polyvinyl alcohol" only qualifies the gel or also qualifies the foam, sponge, swellable polymer, etc (i.e. polyvinyl alcohol gel, polyvinyl alcohol foam, polyvinyl alcohol sponge, polyvinyl alcohol swellable polymer, etc). (2) It is unclear if the acylation derivatives apply only to the hydrogels, or to the other groups (i.e. acylation derivatives of polyvinyl alcohol gels, acylation derivatives of foams, acylation derivatives of sponges, etc). (3) The term "acylation derivative" renders the claim indefinite because it is unclear how far removed the structure of the "derivative" can be from the parent compound without being a different

compound altogether. The dependent claims do not clarify the Markush group or the derivative language, and are indefinite for similar reasons.

Claim 68 recites "the polymer is a hydrogel selected from the group consisting of crosslinked polyethylene oxide, polypropylene oxide, polyvinyl alcohol..." It is unclear if "crosslinked" only qualifies polyethylene oxide or qualifies polyethylene oxide, polypropylene oxide, polyvinyl alcohol, etc (i.e. crosslinked polyethylene oxide, crosslinked polypropylene oxide, crosslinked polyvinyl alcohol, etc). The dependent claims do not clarify the Markush group and are indefinite for similar reasons.

Claim 82 recites the limitation "the biopsy site relocating step" in claim 81. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 61, 65-73, 75-83 and 86-89 are rejected under 35 U.S.C. 102(b) as being anticipated by US 20020188196 ('196). '196 discloses a method of marking a biopsy site within a subject's body, comprising depositing an implantable biopsy cavity marking device comprising at least one body comprising a resilient biocompatible material, wherein the marking device is radiopaque and echogenic, wherein the biocompatible material is formed by a slurry comprising a solid echogenic polymer powder suspended in a liquid, wherein the act of depositing comprises injecting the slurry into the biopsy site (see abstract; paragraphs 11-14, 41, 43, 75 and 77). Binding agents, such as polyvinyl alcohol and a hydroxy ethyl methacrylate hydrogel, may be added to the biocompatible composition (see paragraphs 48 and 76). Although '196 does not explicitly state that the biocompatible material is effective to form a gel upon introduction within the body of an animal, nor that it forms a gel upon introduction within the body of an animal after contact with a biocompatible liquid, a composition cannot be separated from its properties, and the biocompatible material would inherently have this property. This satisfies instant claims 69-73. See MPEP § 2112. The slurry is formed in a delivery tube and/or within a syringe, and injected through a biopsy needle (a hollow member) (see paragraphs 77, 79-80, and 85). The biocompatible material prior to delivery is reasonably at room temperature. The biocompatible material after delivery is reasonably either at body temperature or at least between room temperature and body temperature. This increase in temperature from before and after delivery satisfies instant claims 79-80. '196 teaches the applicability of the method to

marking and treating breast cancer (see paragraph 3). The biopsy device is imaged with ultrasonic imaging while the device is being inserted into the patient's breast and activated to remove a sample of suspicious breast tissue (see paragraph 9). '196 teaches addition of pharmaceutical agents to the biocompatible material to promote healing, prevent infection, and to help treat any cancer cells remaining near the biopsy site (see paragraph 89). This satisfies claims 83, 86, and 89. Chemotherapy agents are contemplated for this purpose (see paragraph 36). This satisfies instant claim 87. '196 teaches that the biopsy site can be relocated at a later time by finding the polymer (see paragraphs 5, 9 and 14). This satisfies instant claim 88.

Claim 65 has been objected to for failing to further limit claim 61 (see ***Claim Objections*** above). For the purposes of comparing claim 65 to the prior art, the Examiner is interpreting the claim to mean "wherein the biocompatible material further comprises an additional polymer". The polyvinyl alcohol and/or hydroxy ethyl methacrylate hydrogel of '196 satisfy this additional polymer.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is

filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

March 14, 2009